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10/508,958	12/12/2005	Yoshinori Naoe	259908US0XPCT	7546

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
05/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/508,958	NAOE ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending. Claims 8-11 and 16-20 are withdrawn.

Applicant's election with traverse of Group I, claims 1-7 and 12-15, in the reply filed on February 22, 2007 is acknowledged. The traversal is on the ground(s) that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. The Authority did not take the position that unity of invention was lacking in the International application and examined all claims together. Additionally, the Office has not shown that a burden exists in searching the entire application.

This is not found persuasive because this is a national stage application and thus upon examination of the claims the Examiner found that a lack of unity was appropriate for reasons in the previous office action. Additionally, showing a search burden is not necessary in a national stage application. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 12-15 are rejected under 35 U.S.C. 101 based on the theory that the claims are directed to neither a method of making nor a method of using, but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101, which is drafted so as to set forth the statutory classes of invention. 35 U.S.C.101 clearly states, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." The term process as defined by 35 U.S.C. 101 means "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter,

or material." This is not interpreted to mean that a patent can be issued on a process of preparation and a method of use. A patent is given to any new and useful process not processes. Thus, Claims 12-15 are rejected under 35 U.S.C. 101 for the reasons stated above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-15 provide for the use of a compound of the formula (I) for the production of a therapeutic agent of kidney cancer, but since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Thus, claims 12-15 are rejected under 35 U.S.C. 112, second paragraph.

For compact prosecution, the claims have ~~not~~ been interpreted to be a method of treating kidney cancer. The Examiner may ask for restrictions or/and further rejections based on the applicant's response.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 1-7 and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of copending Application No. 11/064,292 ('292). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '292 teaches a method of treating a tumor patient comprising administering to a patient the compound of formula (I) (see claims 1, 2 and 9) or FK 228 (i.e. the stereoisomer of formula (I); current applications compound of formula (II); see claim 3). For clarification, the specification discloses that a patient is a human and administration intravenously (i.e. *in vivo*; see page 17, lines 15-20).

The application '292 does not specifically disclose the suppression of a cancerous tumor in the kidney.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the application '292 and the suppression of a cancerous tumor in the kidney because kidney cancer is treated by the application '292.

(2) Claims 1-7 and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-62, 69 and 70 of copending Application No. 10/948,288 ('288). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '288 teaches a method of treating cancer or a tumor of the kidney comprising administering to a subject in need an effective amount of the compound of formula (I) (see claims 60-62 and 69) or FK 228 (i.e. the stereoisomer of formula (I); current applications compound of formula (II); see claim 70). The method is administered orally, parenterally, intranasally, pulmonarily, vaginally, or transrectally (i.e. *in vivo*; see claims 75-77). For clarification, the specification discloses that a subject is a human (see page 16, lines 31-34 to page 17, line 1).

The application '288 does not specifically disclose the suppression of a cancerous tumor in the kidney.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the application '288 and the suppression of a cancerous tumor in the kidney because kidney cancer is treated by the application '288.

(2) Claims 1-7 and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 60 of copending Application No. 10/486,833 ('833) in view of Georges et al (US 2002/0065282 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '833 teaches a method of treating prostate cancer comprising administering an effective amount of the compound of formula (I) (see claim 45) or a compound of formula (II) (see claim 60). For clarification, the specification discloses that the method is administered to a human intravenously, intramuscularly or orally (see page 11, lines 16 and 17).

The application '833 does not a treatment for kidney cancer or the suppression of a cancerous tumor in the kidney.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the prostate as well as solid tumors of the kidney with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the application '833 and the treatment of kidney cancer because Georges et al. teaches that histone deacetylase inhibitors treats prostate and kidney cancer. Since the applicant's compound is a histone deacetylase inhibitor, then by the same mechanism, the compound will also treat kidney cancer and suppress cancerous tumors in the kidney.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 1-5, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. (Experimental cell research, 1998, 24, pages 126-133) in view of Georges et al (US 2002/0065282 A1).

Nakajima et al. teaches the compound of formula I and II as an inhibitor of intracellular histone deacetylase activity (see title, abstract, lines 15 and16, and page 127, figure 1) that strongly inhibits proliferation of tumor cells *in vitro* and greatly suppresses the growth of transplanted tumors in mice (see page 126, column 2, last 4 lines; addresses claims 1-5 and 12-14).

Nakajima et al. does not teach a treatment for kidney cancer or the suppression of a cancerous tumor in the kidney.

Georges et al. teaches a method of treating the proliferation of malignant cell and cancer of the breast, lung, colon, rectum, stomach, prostate, bladder, pancreas, ovary as well as solid tumors of the kidney, liver, prostate and pancreas with a histone deacetylase inhibitor (see page 3, paragraph 36, lines 8-10, 18 and 19).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine Nakajima et al. and the treatment of kidney cancer because Georges et al. teaches that histone deacetylase inhibitors treats prostate and kidney cancer. Since the applicant's compound is a histone deacetylase inhibitor, then by the same mechanism, the compound will also treat kidney cancer and suppress cancerous tumors in the kidney. Additionally, without unexpected results, one skilled in the art would reasonably expect that an anti-tumor drug would treat a tumor in the kidney.

(2) Claims 6, 7, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. (Experimental cell research, 1998, 24, pages 126-133) in view of Georges et al (US 2002/0065282 A1) as applied to claims 1-4,

12 and 13 above in view of Ueda et al. (The Journal of Antibiotics, 1994, vol. 43(3), page 301-310).

Nakajima et al. and Georges et al. teachings are as applied to claims 1-4, 12 and 13 above.

Nakajima et al. and Georges et al. does not teach the applicant's compound *in vivo* or in a human.

Ueda et al. teaches the applicants compound of formula I and II as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine Nakajima et al. and suppressing the growth of cancerous tumors of the kidney *in vivo* in a human because Ueda et al. teaches the applicant's compounds as anti-tumor agents against human tumor cell lines both in vitro and in vivo (see page abstract lines 1, 4 and 5, and page 302, figure 2).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER